NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE S.A., et al.,	CIVIL ACTION NO. 11-3962 (MLC)
Plaintiffs,	**MEMORANDUM OPINION**
v.	
DR. REDDY'S LABORATORIES, LTD., et al.,	
Defendants.	

COOPER, District Judge

This is an action arising under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2)(A). Plaintiffs, Helsinn Heathcare S.A. ("Helsinn") and Roche Palo Alto LLC ("Roche") (collectively, "plaintiffs"), are assignees of U.S. Patents No. 7,947,724 ("'724 patent"), No. 7,947,725 ("'725 patent"), No. 7,960,424 ("'424 patent"), and No. 8,598,219 ("'219 patent"). The four patents-in-suit are listed in the FDA "Orange Book" as covering plaintiffs' product Aloxi®, which is a pharmaceutical composition containing the active ingredient palonosetron. The version of Aloxi® currently marketed by plaintiffs is an intravenous solution with approved indications for preventing or treating cancer chemotherapy-induced nausea and vomiting.

Plaintiffs brought this action, and related consolidated actions, against generic drug manufacturers, Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc.

("DRL"), Sandoz, Inc. ("Sandoz"), Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. ("Teva"). Plaintiffs alleged that each group of defendants had filed an Abbreviated New Drug Application ("ANDA") containing so-called "Paragraph IV" certifications asserting that the claims of the patents-in-suit were invalid and/or not infringed. The asserted claims are claims 2 and 9 of the '724 patent, claim 2 of the '725 patent, claim 6 of the '424 patent, and claims 1, 2, and 6 of the '219 patent. The pertinent limitations of the first three patents are "reducing emesis...," the "0.05 mg/mL" concentration, and "EDTA." The pertinent limitations of the '219 patent are "reduce ... cancer chemotherapy-induced nausea and vomiting," "0.25 mg" dose in "5 mL ... solution," and "EDTA."

Defendant Sandoz was dismissed from the action by consent, on December 31, 2014. (Dkt. 247.)[1] The Court issued a memorandum opinion construing certain preamble language in the '219 patent claims, on April 22, 2015. (Dkt. 290.) An 11-day bench trial was conducted in June, 2015, with closing arguments presented on August 12, 2015. (Dkts. 320, 322, 324, 326, 328, 330, 331, 337, 340, 342, 344, and

[1] The Court will cite to the documents filed in this case in the Electronic Case Filing System ("ECF") by referring to their docket entry numbers by the designation of "dkt." References to docketed materials are to their ECF pagination. The two later-filed actions that have been consolidated into this lead case are Civil Actions No. 11-5579 and No. 13-5815. Copies of the four patents-in-suit are attached as exhibits to the pleadings, and are trial exhibits. We will simply cite to the patents by page or column and line number.

353.) Defendant DRL was dismissed on stipulation on October 16, 2015. (Dkt. 355.)[2] Thus, the current parties in this case are plaintiffs and Teva.

Teva asserts that the asserted claims of each of the four patents-in-suit are invalid as obvious under 35 U.S.C. § 103. Teva also raises a written description claim against those patents under 35 U.S.C. § 112. Teva further asserts invalidity of those patents under the on-sale bar provision of 35 U.S.C. § 102. The on-sale bar issue presents not only underlying factual questions, but also a statutory interpretation question addressing the amended text of § 102(a)(1) under the America Invents Act ("AIA"), Pub.L. No. 112-29 (2011). Plaintiffs oppose each of Teva's points on those issues, asserting that the patents are valid and enforceable.

There is also an infringement issue. Teva filed one consolidated ANDA, seeking approval for products at two different dose levels (0.25 mg and 0.075 mg), and two different treatment indications (chemotherapy-induced nausea and vomiting ("CINV") for the 0.25 mg dose, and post-operative nausea and vomiting ("PONV") for the 0.075 mg dose). The concentration of both proposed Teva products is 0.05 mg/mL, because the 0.25 mg dose solution is 5 mL and the 0.075 mg dose solution is 1.5 mL.

---

[2] DRL and plaintiffs have a related action, actively pending in this Court, pertaining to the '724 patent and DRL's pending 505(b)(2) New Drug Application under 21 U.S.C. § 355(b)(2). See Helsinn Healthcare S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al., Civil Action No. 12-2867. In that case, the Court issued a Memorandum Opinion and Order on April 2, 2015, construing the '724 claim term "a chelating agent." (Civ. Action No. 12-2867, dkt. 91 (Order) and 92 (SEALED Mem. Op.).)

The asserted '219 patent claims only specify a 0.25 mg dose, in a 5 mL volume (i.e., concentration 0.05 mg/mL), for CINV. Plaintiffs assert that if the '219 claims are held to be valid, those claims are infringed by Teva's ANDA filing itself, according to the Hatch-Waxman Act, and therefore both generic products applied for in Teva's ANDA must infringe and be enjoined. Teva disputes plaintiffs' legal position and seeks a declaration that its 0.075 mg dose PONV product will not infringe the asserted '219 patent claims.

This Memorandum Opinion constitutes the Court's findings of fact and conclusions of law, pursuant to Federal Rule of Civil Procedure 52(a). For the reasons set forth herein, the Court finds: (1) the person of ordinary skill in the art ("POSA") would be defined as plaintiffs proposed, including skills of a clinician, marketing person, formulator, and pharmaceutical development scientist; (2) the framing of the obviousness issue would be whether it would have been obvious to a POSA in January, 2003 to develop an improved intravenous antiemetic formulation containing palonosetron and (in particular) EDTA; (3) based on the prior art, the selection of palonosetron for development would not have been obvious; (4) based on the prior art, the selection of dosage 0.25 mg for CINV would not have been obvious; (5) based on the prior art, the selection of 0.05 mg/mL concentration would be dose-dependent and would not be obvious; (6) the asserted claims would not have been arrived at by "routine experimentation"; (7) evidence including commercial success attributable to

the claimed formulation, industry skepticism, and long-felt need supports the finding of non-obviousness; (8) the asserted claims are not invalid for lack of written description; (9) the asserted claims were not ready for patenting as of January, 2002; (10) all three pre-January 2002 Helsinn contracts (including the MGI contract, which we find was a contract) meet the "sale or offer for sale" criteria under the pre-AIA on-sale bar test; but (11) none of the three pre-January 2002 Helsinn contracts meet the post-AIA on-sale bar test, as the Court interprets and applies the amended statutory language of 35 U.S.C. § 102(a)(1), because the Oread and SP contracts were entirely confidential, and although the existence of the MGI contract was announced publicly, the claimed invention itself was not disclosed; (12) the asserted claims of the '724, '725, and '424 patents would be infringed by sale of Teva's proposed 0.25 mg/5mL CINV product and 0.075 mg/1.5mL PONV product, as the parties have stipulated; (13) the asserted claims of the '219 patent would be infringed by sale of Teva's proposed 0.25 mg/5mL CINV product, as the parties have stipulated; and (14) the asserted claims of the '219 patent would not be infringed by sale of Teva's proposed 0.075 mg/1.5mL PONV product.

Based on these factual findings, the Court concludes (under the applicable standards of proof on each issue) as follows: (1) Teva did not prove that the '724, '725, '424, or '219 patents are invalid as obvious under § 103, or for lack of written description under § 112; (2) as to Teva's on-sale bar claim of invalidity of the '724,

'725, and '424 patents under the pre-AIA § 102(b), Teva proved the "sale or offer to sell" prong as to the Oread, SP, and MGI contracts, but Teva did not prove that the claimed invention was "ready for patenting" as of January 30, 2002; therefore, Teva did not prove that the '724, '725, and '424 patents are invalid under the on-sale bar; (3) Teva did not prove that the '219 patent is invalid under the post-AIA § 102(a)(1) on-sale bar; (4) assuming that the '724, '725, and '424 patents are valid as the Court has found, the Court agrees with the parties' stipulation that both the 0.075 mg dose and the 0.25 mg dose generic product specified in Teva's ANDA will infringe those three patents; (5) assuming that the '219 patent is valid as the Court has found, the Court agrees with the parties' stipulation that the 0.25 mg dose generic product specified in Teva's ANDA will infringe the '219 patent; and (6) assuming that the '219 patent is valid as the Court has found, the Court further finds that plaintiffs did not prove that the 0.075 mg dose generic product specified in Teva's ANDA will infringe the '219 patent.

Based upon these findings and conclusions, the Court will enter judgment declaring that:

(1) the asserted claims of the '724, '725, and '424 patents are valid and are infringed by both Teva's proposed 0.25 mg and 0.075 mg generic products;

(2) the asserted claims of the '219 patent are valid and are infringed by Teva's proposed 0.25 mg generic product; and

(3) the asserted claims of the '219 patent are valid and are not infringed by Teva's proposed 0.075 mg generic product.

This Memorandum Opinion will be filed under temporary seal, and will be unsealed on or after December 1, 2015, unless a motion to seal is filed by any party. The Court will enter an appropriate judgment.

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge

Dated: November 13, 2015